UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804
	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO "GENERIC MANUFACTURERS'" MOTION FOR PARTIAL SUMMARY JUDGMENT

July 31, 2019

***In re National Prescription Opiate Litigation*: MDL 2804**
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Opposition To "Generic Manufacturers'" Motion For Partial Summary Judgment (PSJ8 – Generic's Opp)

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Movants Mallinckrodt, Teva, Allergan, and Endo, collectively manufactured more than 68 billion opioid pills between 2006-2012 - primarily generics - accounting for more than 88 percent of the opioids sold in the U.S. during that period. To achieve these startling numbers, Defendants engaged in aggressive and misleading marketing, among other wrongful conduct. Nevertheless, Defendants have moved for partial summary judgment, arguing that no claim relating to their opioids marketing can proceed to trial because (1) they didn't do it; and (2) federal law preempts any state law claim arising from marketing conduct.

Defendants' first argument is wrong: as detailed in Plaintiffs' brief, Defendants and other members of their corporate families engaged in a coordinated, aggressive, and misleading marketing scheme. Their misconduct included misleading "unbranded" marketing (i.e. marketing of opioids generally without reference to a specific opioid product), as well misleading specific marketing of branded and generic opioids. Defendants marketed opioids to physicians, patients, pharmacists, and other participants in the supply chain through direct marketing, paying KOLs, secretly funding front groups, and other means. These efforts worked; they shifted prescribers' and patients' historically negative perceptions of opioids, vastly expanding the U.S. and Ohio market for branded and generic opioids.

Defendants' preemption argument is also without merit: This Court has already ruled that such marketing claims are viable against these Defendants.[1] Moreover, contrary to Defendants' mischaracterization of Plaintiffs' claims, Plaintiffs do not contend that these Defendants should have changed the product labeling, which claims might be preempted by federal law. Instead, Plaintiffs' claims arise from Defendants' myriad other aggressive and misleading marketing tactics, to which the preemption doctrine and the cases Defendants rely on have no application.

Finally, Defendants' motion fails to move the litigation meaningfully towards resolution. Even read broadly, Defendants' motion would have no impact on the bulk of Plaintiffs' claims, including under RICO and arising from Defendants' failure to satisfy their duties as DEA registrants to stop diversion and to monitor for suspicious orders. Instead, the motion would, at best for Defendants, pick off small subsets of claims—or, more precisely, parts of claims

In short, Defendants' sold billions of opioids pills, including hundreds of millions to residents of Cuyahoga and Summit counties, for billions of dollars in profit. Their misleading and aggressive conduct is actionable. Defendants' have failed to establish their entitlement to summary judgment. The Court should deny Defendants' motion.

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[1] R. & R. at 42, Apr. 1, 2019, Dkt. # 1499 (Dkt. #*Muscogee (Creek) Nation v. Purdue L.P.*) (noting that "preemption does not bar any of Plaintiff's state law claims to the extent that they are founded upon allegations that the Generic Manufacturers engaged in aggressive and misleading marketing"); *see also* R. & R. at 12-13, Apr. 1, 2019, Dkt. # 1500 (*Blackfeet Nation v. AmerisourceBergen Drug Corp.*) (adopting ruling in *Muscogee Nation* order).

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INTRODUCTION

The four Defendant groups here moving for summary judgment, Mallinckrodt, Teva, Allergan, and Endo, collectively manufactured more than 68 billion opioid pills between 2006 and 2012.[1] This reportedly led to a "surge of legal pain pills that fueled the prescription opioid epidemic, which has resulted in nearly 100,000 deaths from 2006 through 2012".[2] As the *Washington Post* also noted, "three companies that are now controlled by large multinational drugmakers: SpecGx, a Mallinckrodt subsidiary; Par Pharmaceutical, owned by Endo Pharmaceuticals; and Actavis, part of Teva Pharmaceutical Industries," "manufactured 88 percent of the opioids." *Id.* Those three entities are among the "Generic Manufacturers"[3] now moving for partial summary judgment. As a basis for their motion, Defendants argue that, as a matter of fact and law, no claim relating to their opioids marketing can proceed to trial because (1) they didn't do it; and (2) federal law preempts any state law claim arising from marketing conduct. Both arguments are without merit: Defendants engaged in aggressive and misleading marketing; and claims based on that conduct, which are not predicated on a claim of failure to change product labeling, are not preempted.

As an initial matter, Defendants' motion entirely mischaracterizes Plaintiffs' theory of liability. Plaintiffs have developed substantial evidence establishing that Defendants engaged in aggressive and misleading marketing. This Court has already ruled that such marketing claims, brought against the broader "Marketing Manufacturer Defendants," are viable against these

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[1] Scott Higham *et al.*, *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, Wash. Post (Jul. 17, 2019), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html?utm_term=.48c8d33753f1 ("*76 billion opioid pills*").

[2] *Id.* and Aaron C. Davis *et al.*, *Little-known makers of generic drugs played central role in opioid crisis, records show*, Wash. Post (July 27, 2019), https://www.washingtonpost.com/investigations/little-known-generic-drug-companies-played-central-role-in-opioid-crisis-documents-reveal/2019/07/26/95e08b46-ac5c-11e9-a0c9-6d2d7818f3da_story.html?utm_term=.5a64a5cecda0.

[3] Plaintiffs will refer to the various entities and Defendant group using the same terms as "Generic Manufacturers" footnote 1 of their Mem. in Supp. of Mot. for Partial Summ. J. (Dkt. # 1749-2) ("Defs.' Mem.").

Defendants. R. & R. at 42, Apr. 1, 2019, Dkt. # 1499 (Dkt. #*Muscogee (Creek) Nation v. Purdue L.P.*) (noting that "preemption does not bar any of Plaintiff's state law claims to the extent that they are founded upon allegations that the Generic Manufacturers engaged in aggressive and misleading marketing") *adopted in part, overruled in part by* Op. and Order, June 13, 2019, Dkt. # 1680; *see also* R. & R. at 12-13, Apr. 1, 2019, Dkt. # 1500 (*Blackfeet Nation v. AmerisourceBergen Drug Corp.*) (adopting ruling in *Muscogee Nation* order) *adopted in part, overruled in part by* Op. and Order, June 13, 2019, Dkt. # 1680.

Moreover, Defendants' argument they cannot be held liable for selling pills into a market "created by alleged false marketing of brand name prescription medicines by other companies." Defs.' Mem. at 3. Is belied by the facts: it was not only "other companies" that created the extraordinary market for opioid drugs, these Defendants substantially contributed to it. Each moving entity is or was part of a Defendant group that aggressively marketed "brand-name" opioids in such a way as to promote alongside their own generics.[4] Each moving Defendant and their corporate brethren falsely marketed brand-name drugs for which they also sold the generic counterparts, including paying "key opinion leaders," "front groups," and other entities to shift prescribers' and patients' historically negative perceptions of these addictive drugs. They embarked on a decades-long coordinated, aggressive, and misleading marketing campaign to establish and grow the prescription opioid market.

Defendants' assertion that the Court should apply to a broad swath of Defendants' conduct its narrow preemption finding in the *Muscogee Nation* and *Blackfeet Nation* actions is similarly

[4] For a detailed discussion of the corporate history and interrelationships among:

(1) Allergan entities, *see* Pls.' Mem. in Opp. to Allergan Defs.' for Summ. J., filed contemporaneously herewith;

(2) Mallinckrodt entities, *see* Pls.' Opp. to Mallinckrodt plc's Mot. to Dismiss for Lack of Personal Jurisdiction, Dkt. # 1717, refiled as Dkt. # 1812.

(3) Teva entities, see Pls.' Opp. to Teva's Mot. for Summ. J., filed contemporaneously herewith; and

(4) Endo/Par entities, *see Summit* Third Am. Compl. Unredacted Filed Under Seal (Dkt. # 1465) at 24-25; *Cuyahoga* Third Am. Compl. and Jury Demand (Dkt. # 1630) at 21-23.

misplaced. *See* Defs.' Mem. at 3, 5, 11. Plaintiffs do not ask the Court to reconsider the narrow rulings of law made in those reports and recommendations. The preemption ruling in the tribal cases has no application to Plaintiffs' legal theories here because Plaintiffs do not assert the Generic Defendants should have made labeling changes. Instead, Plaintiffs' claims arise from Defendants' myriad other aggressive and misleading branded and unbranded marketing tactics detailed below.[5]

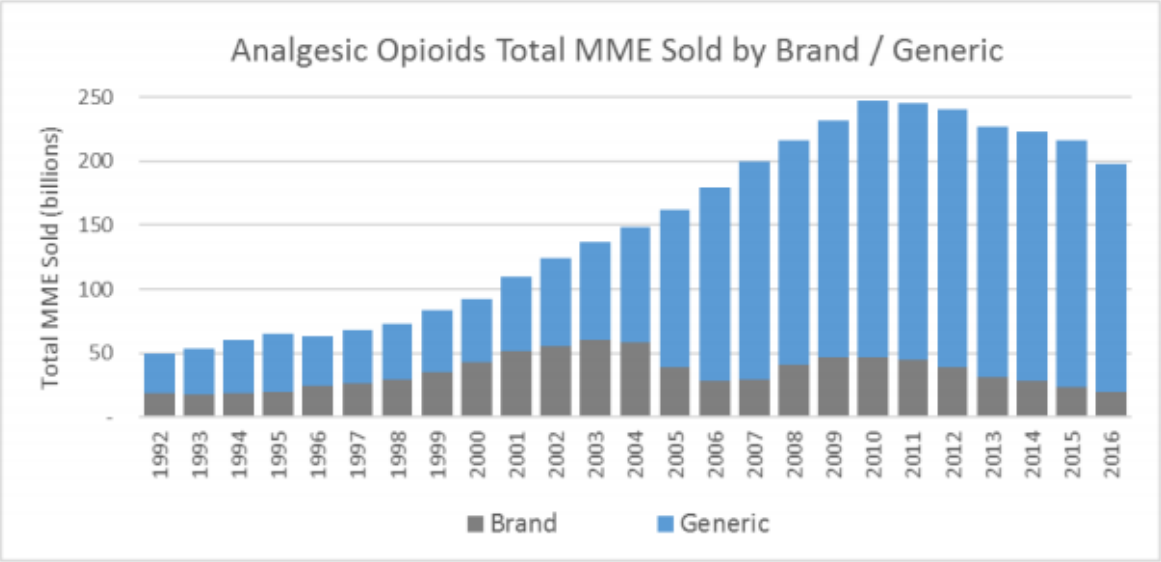
In short, through false and misleading messaging, these Defendants and their corporate families affirmatively sought to change the way this country perceived the inherent risks of opioids. Their efforts were wildly successful. These companies sold hundreds of billions of pills to Americans, including hundreds of millions to residents of Cuyahoga and Summit counties, for billions of dollars in profit. Their motion should be denied.

BACKGROUND

The modern rise of prescription opioids began in the late 1990s, as Purdue Pharmaceuticals and the Sackler family "invented" OxyContin and sold it as a pain-killing wonder drug. As these and other Defendants saw the potential size of this new "pain" market, they developed a new class of brand name opioids, many of which became top sellers, and the subject of much litigation. *See, e.g.*, *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 712 (N.D. Ill. 2016) (describing the intellectual property history of Endo's "Opana ER" drug). As the brand name drugs' patents expired, were successfully challenged in court, or licensed to other companies, generic versions of the opioids took over. Each moving entity (and their allegedly-overseas parents) has made hundreds of millions of dollars—in some cases billions of dollars—from the now vast market for generic opioids. These

[5] Even read most broadly, Defendants' instant motion would have no impact on the bulk of the claims against them, including RICO claims and claims arising from Defendants' complete failure to satisfy their duties as DEA registrants to stop the theft or diversion of opioids, or to monitor for suspicious orders. Mem. in Supp. of Pls.' Mot. for Partial Summ. Adjudication of Defs.' Duties Under the Controlled Substances Act. Defendants' piece-meal strategy of seeking to pick off small subsets of claims—or, more precisely, parts of claims—fails to move the litigation meaningfully toward resolution. Fed. R. Civ. P. 1 (The Rules "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.").

entities are now the volume giants of the opioids market, selling hundreds of billions of "milligram morphine equivalents" ("MME") of generic opioids as the brand names fade away. A 2018 study by the Food and Drug Administration found that while generics made up just over half of the prescription opioid market in 2000, they accounted "for over 90% of MMEs sold in 2016."[6] The steady replacement of brand names by generics is demonstrated in the graph produced by the FDA:



Id.

The moving Defendants do not mention it, but each of them is, or was, part of a larger group that marketed and sold brand-name opioids in such a way as to also promote the generics, and each benefitted from the corporate acts to increase the overall market for opioids. For example, Mallinckrodt made and distributed the brand name prescription opioids Exalgo, Roxicodone, and Xartemis XR alongside its generics, which later included generic Exalgo. *See* Ex. 2 (MNK-T1_0005574545) (listing products). Teva first developed the market for the Actiq fentanyl lollipop and Fentora and then supplemented with the acquisition of a massive generics business from

[6] Ex. 1 (*FDA Analysis of Long-Term Trends in Prescription Opioid Analgesic Products: Quantity, Sales, and Price Trends*, FDA (March 1, 2018), https://www.fda.gov/media/111695/download at 2).

Allergan, a company which also marketed and sold both brand (Kadian and Norco) and generic (fentanyl, morphine sulphate, hydrocodone, oxycodone and oxymorphone) opioids until its sale of the generic business in 2016. *See* Pls.' Opp. to Allergan Defs' Individual Motion for Summ. J. Finally, Endo sold Opana, Opana ER Percodan, and Percocet brand-name opioids alongside its generics—which included a generic of Percocet, under the registered trademark Endocet.[7] Volume- and revenue-wise, however, Defendants' generics products far outpaced their brand-name opioid drugs.

I. DEFENDANTS FALSELY PROMOTED THEIR OPIOID PRODUCTS

The record evidence establishes that Defendant Generic Manufacturers made countless misleading statements about the safety and efficacy of opioid use, transforming the standard of care for the treatment of pain. *See* Report of Anna Lembke, M.D., Dkt. # 2000-10, at 10-21. The misstatements were made to a wide audience of patients, prescribers, pharmacists, retail chain stores, other industry representatives, and the public at large. This conduct drove demand for opioids overall, which resulted in a dramatic increase in opioid sales—most of which were generic.

Much of this misleading promotion falls into the category of "unbranded" marketing—marketing that is not tied to a specific product or label (generic or branded), but, instead promotes opioid use generally. Defendants marketed opioids generally by overstating the safety and efficacy of opioid treatment while downplaying addiction and other risks. Defendants disseminated materials promoting broad opioid use through a variety of means, including industry trade shows and conferences, mailings and advertisements in journals, and funding patient advocacy or "front groups," speakers, and ghost-writing continuing medical education ("CME") presentations.

Defendants, each of which marketed both brand and generic opioids, claim they only conducted unbranded marketing regarding their name-brand opioid products, and not their generic

[7] Ex. 3 (ENDO_DATA-OPIOID_MDL-00000035); *see also* Ex. 28 (Endo Pharms. Holdings Inc., 2001 Annual Report (Form 10-K) (Mar. 29, 2002) at 4, 6, & 7.

opioid products. But unbranded marketing is just that—it benefits all opioid products, both branded and unbranded (generic). *See* Report of David Kessler, M.D., Dkt. # 2000-8, at ¶¶ 138-138.2 (Purdue), ¶¶ 216-216.8 (Endo), ¶¶ 555-555.2 (Mallinckrodt); David Kessler Dep. Tr. (Vol. II 04/26/19), Dkt. # 1963-15, at 635:10-636:20, 661:6-23, and 702:12-703:2. By promoting opioids for many kinds of patients and minimizing the risks associated with those drugs with their unbranded marketing, Defendants raised demand not just for their name-brand opioids but for all their opioid products. Defendants cannot credibly argue otherwise since generic drugs are required to be functionally the same as the branded drugs on which they are based—hence, if a doctor is told that a branded opioid is safe and effective for pain, with a low risk of abuse and addiction, the same misrepresentation would automatically apply to a generic version of that branded drug.[8]

Defendants also claim that they did not promote their generic opioids to doctors. As described below, this statement appears to be false. But even if certain Defendants did not directly promote their generic opioid products to doctors, which it appears that at least some of them did, detailing physicians was not the only avenue for misrepresentations about the safety and efficacy of opioids. Defendants also marketed their products to pharmacists, national retail chains, and others in the supply chain using marketing materials that misrepresented the safety and efficacy of opioids for pain. This marketing contributed to increasing demand for Defendants' products and helped ensure the opioids market would continue to expand. In short, Defendants' false messaging expanded the market for both branded and generic opioids.

[8] For a further discussion of Defendants' misleading marketing efforts, including their unbranded marketing, *see* Pls.' Consolidated Opp. to Defs.' Mots. on Proof of Causation filed concurrently herewith, which Plaintiffs incorporate by reference here.

A. MALLINCKRODT

Mallinckrodt, through its subsidiary now known as SpecGx LLC,[9] was the largest opioid manufacturer in the country from 2006-2012. SpecGx manufactured over 28.8 billion pills, yielding a market share of 37.7%. *See supra* note 1, *76 billion opioid pills*. More than 135 million of these pills were supplied to Cuyahoga County, and more than 168 million to Summit County. *Id.* The vast majority of these pills were generic. This massive market share was not happenstance—Mallinckrodt engaged in a variety of marketing activities designed to misrepresent the safety and efficacy of opioid use, thereby increasing the demand for all opioids, while also taking steps to satisfy this demand by flooding the market with massive amounts of its generic products. As set forth in Plaintiffs' Opposition to Mallinckrodt's Motion for Partial Summary Judgment (Dkt. # 1812) (incorporated by reference here), Mallinckrodt promoted its generic opioid products at trade shows and conventions, distributed "unbranded materials" to physicians and patients, and promoted its branded products to physicians. All of these promotional activities involved the use of misleading marketing materials, and were designed to increase the overall consumption of opioids, which Mallinckrodt could then satisfy through its massive generic sales.

At industry trade shows and conferences, Mallinckrodt's generics sales representatives—called National Account Managers (NAMs)—distributed pain management "pocketcards" that contained fundamental misrepresentations about the use of opioids, such as the purportedly low risk of addiction, no ceiling dose, treating "breakthrough pain" with more opioids, and using long-acting and short-acting opioids together. The pocketcards expressly stated that "***addiction rarely occurs unless there is a hx [history] of abuse***" and encourages higher doses by stating "[m]ost opioid agonists have ***no analgesic ceiling dose***" and further encourages prescribers with older adults to

[9] For a discussion of the interrelationship among the Mallinckrodt entities, *see* Pls.' Opp. to Mallinckrodt plc's Mot. to Dismiss for Lack of Personal Jurisdiction (Dkt. # 1812).

"start dose low, go slow ***but go!!***"[10] The pocketcards also tell prescribers to "***always ask*** the patient about the presence of pain and ***accept the patient's report of pain***," and to "[u]se long-acting opioids around the clock for baseline management of persistent pain; Use short-acting opioids PRN (rescue) for breakthrough pain," and that "long- and short-acting opioids may be prescribed together."[11] NAMs distributed these misleading pocketcards as part of their standard convention and trade show materials for years.[12] While this marketing was not specific to any particular product, it was an important tool Mallinckrodt used to promote all of its products, including both branded and generics.

That many of these tradeshows involved pharmacists, as opposed to doctors, is irrelevant. Mallinckrodt focused its generic promotional activities on pharmacists, because they often make product purchasing decisions:

> Because of our activities and interactions in policies and issues with this audience, we have access to the decision makers that can influence the purchase and use of our products as well as influence the education of pharmacists. Partnership with ASHP will enable us to access pharmacists who make purchasing decisions in a variety of health system settings.

Ex. 15 (MNK-T1_0001193724). Mallinckrodt's communication of misleading messages to pharmacists nationwide also contributed to the overall change in the standard of care regarding

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[10] Ex. 4 (MNK-T1_0002183040); *see also* Ex. 5 (MNK-T1_0002159713); Ex. 6 (MNK-T1_0001531484); Calvin Williams Dep. (03-29-2019), Dkt. # 1985-20) at 21:19-18; 205:17-209:22 (emphasis added); Ex. 7 (Williams Dep. Ex. 21).

[11] *Id.*

[12] *See, e.g.*, Ex. 8 (MNK-T1_0002699252) (Convention & Trade Show Standard Marketing Material Order as of 1/30/2011 for NAM Steven Becker, listing Pain Management Pocketcard Set, Pk of 10 per 100 Attendees and Oxford American Pocket Cards Breakthrough Pain); Ex. 9 (MNK-T1_0000972885) (Standard Marketing Material Order from June 2011 listing Pain Management Pocketcard Set in "Bonnie's Kroger List," "Bonnie's Supervalu List," and "Tim's List"); Ex. 10 (MNK-T1_0006632298) (July 14, 2011 email from Senior Sales Coordinator to NAM Bonnie New about shipping Pain Management Pocketcard sets to her for use at MAD Days of Summer Expo, along with morphine brochures, fentanyl lozenge brochures, and fentanyl patch brochures); Ex. 11 (MNK-T1_0004841670) (Same list for Harvard Drug Group Trade Partner Expo 2012); Ex. 12 (MNK-T1_0004826101-102) (May 28, 2014 Bonnie New email and attachment stating, for the H.D. Smith show, "If the Pain Management Cards become available I need 125"); Ex. 13 (MNK-T1_0004862918-919) (July 20, 2015 Lisa Cardetti email and attachment ordering materials for ABC tradeshow including Pain Management Pocketcard Set); Ex. 14 (MNK-T1_0005760129-130) (September 29, 2016 Bonnie New email and attachment ordering 250 of the Pain Management Pocketcard Set for the 2016 H.E.B. show).

opioid use that created the opioid epidemic. Pharmacists communicate with both physicians and patients, as defense expert Sandra Kinsey explained in her expert report:

> Patients receive verbal and written information from their prescriber and pharmacist that detail precautions and side effects associated with opioid use. . . . Besides dispensing prescriptions, pharmacists are an integral part of the communication process between doctor, manufacturer, insurer, regulatory agencies and patient, ensuring efficacy, safety and access to every drug they dispense for every patient to which they extend care. . . . As part of the prescription filling process, a pharmacist often communicates with prescribers regarding an opioid prescription to discuss the drug, strength, dose or frequency of utilization for a specific patient.

Report of Sandra Kinsey, R.Ph, MBA, Dkt. # 1939-17, at 6-7. The misrepresentation of the safety and efficacy of opioid use to pharmacists was a critical part of the process by which an entire generation of healthcare professionals was duped into distributing highly addictive substances and believing it was safe and appropriate to do so.[13]

To be clear, Mallinckrodt's false statements were not restricted to pharmacists; doctors and their patients, were also targets. Mallinckrodt, through its "C.A.R.E.S. Alliance" program, funded the distribution of "unbranded" materials promoting opioid use and containing misleading statements about the safety and efficacy of opioids for pain. These materials, which were not specific to any Mallinckrodt product, were provided to both physicians and patients. The focus of these materials was on promoting increased opioid prescribing and providing false assurances about ways to prescribe opioids "safely" or "responsibly," despite the lack of evidence regarding the effectiveness of long-term opioid therapy.[14]

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[13] In addition to handing out misleading literature at pharmacy meetings, Mallinckrodt's Generics business engaged in activities to promote acceptance of opioid use for chronic pain among pharmacists. Mallinckrodt Generics offered a Continuing Education course entitled, "Pharmacist Pain Management: A Focus on Opioids and Conversion Issues." Ex. 16 (MNK-T1_0004602837); Ex. 17 (MNK-T1_0003284656). Mallinckrodt also routinely sponsored an educational program by the American Society of Consultant Pharmacists (ASCP) Foundation for a five-day "Pain Management Traineeship for Pharmacists." Ex. 18 (MNK-T1_0000905348); Ex. 19 (MNK-T1_0000905350). As another example, Mallinckrodt provided funds to the Johnson County Pharmacy Association in 2005 for a Pain Management Continuing Education Program entitled, "The Pharmacist's Role in Management of Chronic Pain: Focus on Opioids." Ex. 20 (MNK-T1_0001308076).

[14] *See, e.g.*, Ex. 21 (MNK-T1_0001758643) (C.A.R.E.S. Alliance opioid clinical management guide containing misrepresentations related to pseudoaddiction and the ability to manage withdrawal through tapering); Ex. 22 (MNK-

footnote continued on next page

For example, Mallinckrodt's C.A.R.E.S. Alliance actively promoted the book *Defeat Chronic Pain Now!*, by Bradley Galer and Charles Argoff. Mallinckrodt identified the book as an important "Education and Enabling tool for patients," Ex. 23 (MNK-T1_0000098099), and Mallinckrodt's catalog of "patient tools"—materials that were made available to prescribers to provide to their patients—described *Defeat Chronic Pain Now!* as providing "patients with ground-breaking strategies for eliminating the pain of arthritis, back and neck conditions, migraines, diabetic neuropathy, and chronic illness." Ex. 24 (MNK-T1_0001493093) (C.A.R.E.S. Alliance catalog). This book contains multiple misleading statements promoting opioid use for pain while minimizing the risk of addiction:

> "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
>
> "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
>
> "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
>
> "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
>
> "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
>
> "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

Ex. 25 (*Defeat Chronic Pain Now!*) at 174-178.

Mallinckrodt also targeted doctors with misleading messages designed to increase physician comfort with generally prescribing opioids, both branded and generic. At least as early as 2008,

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T1_0003416495) (C.A.R.E.S. Alliance safe use and handling guide for patients taking opioid pain medicine, containing misrepresentations related to pseudoaddiction and the purportedly low risk of addiction).

Mallinckrodt sales representatives used a "Pain Pocketguide" about opioids generally that contained the following false statements:

> Risk of addiction rare Single-entity opioids have no maximum dose but may be limited by side effects" Pseudoaddiction" = Drug-seeking behavior focused on pain relief, due to undertreatment of pain.

Ex. 26 (MNK-T1_0002248919); *see also* Ex. 27 (MNK-T1_0001786865) (using the same pocketguide in 2010, except that by then the guide describe the risk of addiction as "low" rather than "rare"). These fundamental misrepresentations are central to Plaintiffs' allegations and are not specific to a particular branded or generic product. They were designed to change the standard of care for prescribing opioids thereby dramatically increasing opioid demand, which would also directly benefit Mallinckrodt's generic products.

Mallinckrodt's massive generic market share, both in Ohio and nationwide, demonstrates the effectiveness of these efforts. Mallinckrodt's false marketing of its generics, when coupled with an aggressive sales strategy of providing substantial discounts via a system of chargeback payments, and a willingness to supply massive quantities of its products to distributors and pharmacists without regard to the risk of diversion (*see* Pls.' Mem. in Opp. to Mallinckrodt's Mot. for Partial Summ. J. at §§ II & III), all contributed to Mallinckrodt's domination of the market for generic opioids and provide a basis for Plaintiffs' claims.

B. ENDO/PAR

Endo's business model also illustrates the overlap of branded and generic opioid promotion. Since its founding, Endo has relied heavily on sales of oxycodone with acetaminophen, which it has sold both under a brand name (Percocet) and as a so-called "branded generic" (Endocet). Notably, Endo continued to sell Percocet under the brand name even after the product came off patent and was "genericized." Percocet and Endocet together comprised approximately 50% of Endo's net

sales in 2001.[15] Indeed, by 2005, Endo declared it was both "the company that built Percocet" and "the company that Percocet built." *See* Ex. 29 (ENDO-OPIOID_MDL-01139611). Through its marketing, Endo sought to portray itself as a pharmaceutical leader with respect to pain treatment generally; in one of its generic promotional materials, Endo describes itself as "anchored in pain management." Ex. 30 (ENDO-OPIOID_MDL-04814925). Endo moved aggressively to sell both branded and generic opioids. In 2006, at the same time as Endo began marketing its branded extended-release oxymorphone pill, Opana ER, it also began marketing the first generic version of OxyContin.

Endo's marketing efforts were intended to alter well-established physician attitudes toward opioids and to position opioids as suitable treatment for everyday pain, rather than limited to terminal illness or cancer pain. Endo sought to alter physician attitudes towards opioids by "remov[ing] barriers—real and perceived—to prescribers" and "proactively neutraliz[ing] opioid abuse issues." *See* Ex. 31 (ENDO-OPIOID_MDL-02002513), Ex. 32 (ENDO-OPIOID_MDL-04095507 (Risk Management Presentation)) and Linda Kitlinski Dep. (01/15/19), Dkt. # 1963-20) at 113:8-18 and 145:22-145:5. Indeed there was even some direct promotion of generics. *See* George Stevenson Dep. (02/15/19) Dkt. #1971-2, at 277:10-23 (Q: And that's the concept we talked about earlier, right, that the generic does not get marketed to physicians, but there is some sales effort directed by the national account executives to the retailers and wholesalers, correct? [Objection] Stevenson: Yes). Endo understood that it was capable of shifting prescriber attitudes toward pain management in general and opioids in particular through unbranded marketing. *See* Ex. 33 (ENDO-OPIOID_MDL-02344002 CD&E The Critical Connection for Success in 2000 and Beyond). As Carol Ammon, founding CEO of Endo, explained in a 2008 interview, Endo's goal was to "move the whole market towards a change in pain management":

[15] Ex. 28 (Endo Pharms. Holdings Inc., 2001 Annual Report (Form 10-K) (Mar. 29, 2002)[annotated], at 7.

> What we really needed to do is drive as much revenue as we could and there were several essential ingredients in that and one was really leveraging the customer base. And for us that's really getting physicians to be acquainted with our products, but more importantly it's getting physicians who are thought leaders that would *not only talk about our products but would really start to move the whole market towards a change in pain management*. So we then could take the profitability, we could have cash, and then be able to invest in new products that would go into that changing landscape of pain management.[16]

Endo primarily executed this strategy through its National Initiative on Pain Control (NIPC) front group—a national CME program operated through a third party but fully funded and at least partially influenced by Endo. Between 2001 and 2012, Endo provided at least $31 million in funding to support the NIPC and NIPC programming reached over 1.2 million prescribers. *See* Ex. 35 (END00152457); Ex. 36 (MDL_KP360_000000002) (third-party administrator documents reflecting Endo NIPC funding). Endo suggested that NIPC focus on opioids to create the greatest return on investment for Endo. *See* Ex. 37 (ENDO-OPIOID_MDL-02261843). NIPC programs featured multiple misleading messages about opioid use, including that the risk of addiction is low,[17] that signs of abuse are really "pseudoaddiction,"[18] and that opioid use leads to improved function.[19] Stevenson Dep. Dkt. #1971-2, at 214:1-15 ("As I said earlier there's a pie -- there's a brand flavor that converts. Part of that pie converts overtime to the -- well, converts immediately to the generic flavor. The amount it converts increases over time. . . . .The brand promotion creates the pie based on the doctor writing the prescription."), 278:1-9) And Endo's efforts worked: NIPC programming

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[16] Ex. 34 (The 7 Essentials: The Endo Pharmaceuticals Story (Video), 4/8/08, https://www.youtube.com/watch?v=6fqFOy-bZ1k&t=233s) (emphasis added).

[17] Ex. 38 (KP360_OHIOMDL_000011082) (Pain Management Today Vol. 8 # 1, stating "A substantial amount of research indicates that opioid therapy does not lead to addiction in a majority of patients"); Ex. 39 (KP360_OHIOMDL_000002116) (Presentation titled Slides Advances in Opioid Analgesia Part 2, stating "Addiction to opioids in the context of acute pain treatment is rare in those with no history of addictive disorder.").

[18] Ex. 40 (KP360_OHIOMDL_000121628) (Presentation titled Chronic Opioid Therapy, stating "Pseudoaddiction - Pattern of drug-seeking behavior of patients with pain receiving inadequate pain management that can be mistaken for addiction… May resolve with reestablishment of adequate analgesia or adjustment of analgesic dose/schedule").

[19] Ex. 41 (ENDO-OPIOID_MDL-00481936) (Brochure titled "Pain – Opioid Therapy," stating that opioid therapy will "Improve quality of life" and "Your level of function should improve: you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse").

reduced the fear of prescribing opioids and that prescriber attendance at NIPC CME programs had a strong positive correlation with increased prescribing of opioids. Attendees of NIPC sessions stated, among other things, that they would "use [more] opioids," "consider using longer acting agents," and "use opioids earlier with [their] patients." Ex. 42 (MDL_KP360_000000021) (NIPC Executive Summary - NIPC Dinner Dialogue Series). In response to feedback following a NIPC program in Cincinnati, Vin Tormo, Clinical Development and Education Liaison for the Midwest, described the program as "pav[ing] the way" towards opioid prescribing:

> Thanks for the feedback Teresa- glad that the [NIPC] program went so well there!!! Glad that your recommendation to have the opioid program in Cincinnati paved the way towards, and lessened the fear of appropriately prescribing opioids.

Ex. 43 (ENDO-OPIOID_MDL-01928285). Endo's Director of Clinical Development and Education, Linda Kitlinski, added,

> CONGRATULATIONS on working together to really optimize the value of the NIPC programs for the physicians in your area ... As we saw with the return on education study conducted this year, the effectiveness of well-planned CME content and well-executed audience recruitment is truly a "winning combination!"

Id.; *see also* Ex. 44 (ENDO-OPIOID_MDL-0623389) (confirming prescriber attendance at NIPC program was correlated with increased opioid prescribing). During the period it funded NIPC, Endo's opioid sales rose from under $1 billion to over $3.5 billion. Ex. 45 (ENDO-Campanelli-210).

In addition to promoting opioids through NIPC, Endo also advocated for broader opioid use through funding the American Pain Foundation (APF). For example, Endo supported the publication of APF's "Pain Action Guide," which encouraged patients to seek treatment for their pain and emphasized that opioids are effective for relief of pain, including pain. *See* Ex.46 (ENDO-OPIOID_MDL-06234029) (2001 letter from APF to Endo thanking Endo for its support of the "Pain Action Guide" among other initiatives and noting that it is so popular that it has gone into its third printing). The "Pain Action Guide" misleadingly minimized the risk of addiction, stating, "Pain

medications rarely cause addiction . . . . Unless you have a history of substance abuse, there is little risk of addiction when these medications are properly prescribed by a doctor and taken as directed." Ex. 47 (CHI_000435580) (2000 edition); *see also* Ex. 48 (CHI_000432477) (same in 2003 edition).[20]

Many of Endo's marketing materials directed to physicians and patients misleadingly asserted that the risk of addiction from opioid use was low. For example, in a brochure aimed at patients titled, *Taking a Long-Acting Opioid: What Does It Mean to Me?*, Endo minimized the risk of addiction, stating, "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *See, e.g.*, Ex. 51 (ENDO-CHI_LIT-00024520). In another patient brochure, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo assured patients that addiction is something that happens to other people:

> Pain relief is an important medical reason to take opioids as prescribed by your doctor. Addicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.

Ex. 52 (ENDO-CHI_LIT-00084049). Endo also told physicians that proper patient selection would enable them to prescribe opioids safely, misleadingly asserting, "[s]tudies have shown that one of the best ways to limit abuse and misuse is to choose appropriate patients for opioid therapy" and that "proper choice of patient can minimize the likelihood of developing addiction." Ex. 53 (ENDO-OPIOID_MDL-02150882).

In addition, Endo emphasized the supposed "undertreatment" of pain and posited opioids—again, generally, and not any particular opioid product—as the solution: "Undertreatment of pain produces economic and social costs over tens of billions of dollars each year in the U.S. Opioids have been proven to treat pain effectively and thus can help eliminate undertreatment, if used properly." Ex. 53 (ENDO-OPIOID_MDL-02150882).

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[20] In 2010, Endo disclosed over $2 million in funding to APF to the Senate Finance Committee. *See* Ex. 49 (ENDO-OR-CID-00754369) at 24. In APF's annual report from 2010, Endo is listed as a supporter at the "Visionary" level, above any other entity. *See* Ex. 50 (CHI_000430305) at 22.

Endo made sweeping misrepresentations not only about the purportedly low risk of addiction, but also about improved function and quality of life from opioid use, and in both instances falsely claimed the scientific literature supported these statements:

> Multiple studies have confirmed the usefulness of opioids in the treatment of chronic pain and cite the relatively low incidence of abuse and addiction among most patients who receive opioid analgesics. The literature further suggests the potential for increased functioning and improved quality of life significantly outweigh the risk of abuse.

Id.

As with the broad misstatements made by other Generic Defendants, these assertions were not specific to any product and served to create demand for opioids overall—demand that was largely filled by generics. And like other Defendants, Endo pushed rebates and discounts to encourage volume sales of its generic narcotics. In one advertisement, Endo used dollar signs to promote morphine sales:

Ex. 54 (ENDO-OPIOID_MDL-04930147). These promotional tactics, when coupled with broad misrepresentations regarding the safety and efficacy of opioids as a class of drugs, resulted in the sale of massive quantities of generic opioids.

C. ALLERGAN/ACTAVIS

Allergan argues it does not market generic opioids—full stop. It asserts "generic manufacturers . . . avoid marketing to physicians," and thus, because there is "no promotion, there can be no false promotion. . . ." Defs.' Mem. at 1-2. These assertions are unsupported by the record.

Allergan had a sophisticated and well-developed generic marketing program headed by Jinping McCormick, "Director of Generic Marketing." Ms. McCormick's compensation was directly tied to maximizing generic drug sales including generic opioids such as generic Opana ER (oxymorphone ER),[21] generic Kadian[22] (morphine sulphate ER), generic MS Contin (morphine sulphate ER), and generic fentanyl, all of which were among Allergan's top products. Jinping McCormick Dep. (01/09/2019) Dkt. # 1966-19, at 27:22-28:12; 48:20-49:2; 65:9-72:8; Exs. 56, 57 (McCormick Dep. Exs. 4, 22). Indeed, Ms. McCormick was tasked with growing generic sales from $477 million to $535 million from 2010 to 2011. McCormick Dep., Dkt. # 1966-19, 72:24-74:5; Ex. 56 (McCormick Dep. Ex. 4). Notably, the Company sold both brand-name and generic opioids and the generic marketing team led by McCormick worked closely with the brand-name marketing team and its sales force. McCormick Dep., Dkt. # 1966-19, 200:6-19 (working with brand team to target top prescribers for generic Kadian); 205:1-206:21 (same). That sales force was provided with specific targets for the drugs it promoted, i.e., "***1306 Kadian prescriptions per day"*** with "the main messages [being] ***long history of safe and efficacious use***, favorable formulary position and co-pay program." Jennifer Altier Dep. (08/02/2018), Dkt. # 1956-6: 141:5-18; Altier Dep. Ex. 3. This target was set despite a reference in the same email by Allergan's head of marketing for brand drugs, Natalie Leitch, to the CEO Douglas Boothe, that there was "***complete lack of clinical data for Kadian***." Ex. 58 (Altier Dep. Ex. 3).

[21] Generic Opana ER. McCormick Dep., Dkt. # 1966-19, at 74:15-16.

[22] The Actavis parent company bought the brand-name opioid Kadian in 2008 and actively promoted it through early 2013. *See* Pls.' Mem. in Opp. to Allergan Defs.' for Summ. J. at § III.B.2., and *see e.g.*, Ex. 55 (Altier Dep. Ex. 17 (Actavis Group used its Kadian sales representatives to detail and promote generic Opana ER and generic Kadian by targeting high prescribing doctors)).

Allergan's sales force reached out to physicians regarding generic opioids for the sole purpose of maximizing sales. *See, e.g.*, Ex. 59 (Myers Dep. Ex. 16) ("we . . . want to ***target physicians*** to continue to write ***and increase*** their scripts."); McCormick Dep., Dkt. # 1966-19, at 273 (testifying to "extensive promotion" of generics), 200:6-19, Ex. 60 (McCormick Dep. Ex. 12); Altier Dep., Dkt. # 1956-6 at 39:19-42:12, 78:24-79:12 (sales force of about 48 representatives promoted generic Kadian and oxymorphone for most of U.S. through 2012).

McCormick testified about Allergan's vast array of generic opioid marketing strategies. First, Allergan used the same sales representatives that marketed its brand-name drugs, including Kadian, to market its generic opioids, including generic Kadian, directly to physicians.[23] As set forth in Pls.' Mem. in Opp. to Allergan Defs.' for Summ. J., these were the same sales representatives that had already been trained with false messaging regarding branded Kadian and opioids generally. McCormick and Ara Aprahamian (from Generic Sales) participated in training the Kadian sales representative team on marketing generics, and even suggested a "contest" and "bonus plan" for those sales representatives that sold the most oxymorphone ER. Boothe Dep. Dkt. # 1959-6 at 223:4-224:11 ("I would prefer a contest for the top five or ten reps based on percentage group of scripts on [oxymorphone ER]"), 221:5-224:3; Ex. 62 (Boothe Dep. Ex. 14, ACTAVIS0506794-814) ("sales rep training material"). The sales representatives' compensation was directly tied to their ability to maximize sales of ***generic*** opioids as was Ms. McCormick's. Boothe Dep. Dkt. # 1959-6, at 240:16- 241:14; Ex. 62 (Boothe Dep. Ex. 14). Defendants' assertion they did not market generics

[23] Douglas Boothe Dep. (01/17/19), Dkt. # 1959-6, at 228:13-229:13 (admitting they used Kadian sales team to sell generics); Ex. 61 (McCormick Dep. Ex. 6), (Allergan_MDL_00235615)) (referencing regular Monday call with branded and generic marketing teams "encouraging initial feedback from Kadian sales reps" with respect to "Oxymorphone ER"); Ex. 57 (McCormick Dep. Ex. 22) (evaluating as part of "Generic Kadian Update" the "impact of keeping the sales team in the field and what would be required in the way of incremental RX to justify the ongoing expense. . . . The sales team is calling on 5500 prescribers. Each of these prescribers would need to write Kadian for about 1.3 new patients or convert 1.3 patients from generic MS Contin to generic Kadian per month to reach the threshold. Given this same group of prescribers writes more than 200k Rx for generic MS Contin each month and that formulary barriers should be increasingly nonexistent, ***focusing the sales team on generic MS Contin-to-generic Kadian conversions looks like a good strategy***.").

is utterly belied by the fact that they trained their sales representatives with false messaging about branded Kadian and opioids generally, and then had those very same sales representatives market generic Kadian and other generic opioids, with their compensation based on maximizing those generic drugs.

In addition to using their Kadian sales representatives to promote generic opioids including but not limited to generic Kadian, Allergan employed a wide variety of other marketing tools which contributed to its flooding of the market with generic opioids. For example, Allergan engaged in an elaborate media campaign. McCormick Dep. Dkt. # 1966-19, at 273:3-6 and Ex. 63 (McCormick Dep. Ex. 20). The company placed advertisements in a wide variety of magazines which omitted the full extent of the risks of the generic opioids. McCormick explained, "Practical Pain Management falls into this category. . . We also did more specific promotions this year as we discussed earlier. Fentanyl. . . and Oxymorphone are published. ***We did extensive promotion and media campaign for oxymorphone***." McCormick Dep. Dkt. # 1966-19, at 272:15-273:2. The Company ensured the placement of fentanyl and oxymorphone ads in publications such as Chain Drug Review, Pharmacy Times, Practical Pain Management and Drug Store News repeatedly throughout the year. Ex. 63 (McCormick Dep. Ex. 20 (ACTAVIS0346651)) (email attaching spreadsheet showing 2011 Media Plan for certain opioid products); McCormick Dep. Dkt. # 1966-19, at 271:10-21 (targeting pain management physicians by placing advertisements in journal Practical Pain Management).

Also as part of this effort, the generics marketing department worked with an advertising agency to find potential journals to place their advertisements in, including Pain Medicine, Pain Medicine News, the Journal of Pain, the Journal of Pain Symptom and Pain Management and Anesthesiology News—a strategy designed to target physicians and pharmacists. *Id.;* McCormick Dep. Dkt. # 1966-19, at 282:7-21; 273: 7-19. For example, Allergan worked with ad agency Catalyst

to create advertisements/mailers such as the one for fentanyl which make clear fentanyl ***cannot*** be used short-term or occasionally ("for short term or any post-operative pain, or occasional pain") and must only be used long-term ("around-the-clock"). Allergan marketed fentanyl for doses as high as 75 and 100 mcg/h strengths – this marketing was misleading because Allergan said ***nothing*** about risk of addiction or overdose, but rather suggesting customers could "[c]ount on Actavis for quality first-class generics." Ex.64 (Allergan_MDL_02053309-16); *see also* McCormick Dep. Dkt. # 1966-19, at 83:4-21 (remodel of fentanyl ad), 281:8-23 (use of mailers to target physicians and pharmacists). The evidence also suggests Allergan worked with physician-based telemarketing companies such as Triple I, for telemarketing campaigns targeting 9,000 high-prescribing ("high decile") physicians with the Company's Kadian messaging, which would have effectively promoted both brand and generic Kadian that Allergan sold. Ex. 65 (Boothe Dep. Ex. 10) Indeed, Allergan's generic marketing department intentionally capitalized on its false marketing for Kadian by using the branded Kadian logo for the generic Kadian fliers so as to capture the benefit of branded Kadian marketing (which as set forth separately in Plaintiffs' Memorandum in Opposition to Allergan Defendants' Motion for Summary Judgment was false and misleading) for generic Kadian. Ex. 57 (McCormick Dep. Ex. 22 (Allergan_MDL_00396954)) ("I agree with Nathalie that we should use Kadian logo as that's what physicians and patients are familiar with."). Thus, Allergan's false and misleading marketing of branded Kadian was used to maximize sales of generic Kadian.

Allergan also marketed its generic opioid drugs through developing joint marketing plans with distributors like McKesson, for example, on oxymorphone. While the oxymorphone "sell sheet" made clear that the drug could only be used for "continuous around-the-clock opioid treatment *for an extended period of time*" and could not be used short-term or "as needed," the sell sheet was false and misleading because it stated nothing about the dangers of addiction associated with taking opioids long-term. Ex. 66 (McCormick Dep. Ex. 17) (emphasis added). Indeed, in one email

discussing the advertisement, Ms. McCormick asks McKesson whether the requirement to include safety information in a fax blast would be different if they omitted the Actavis logo, suggesting that including the safety information was not a high priority for the generics marketing department. Ex. 66 (McCormick Dep. Ex. 17) at 00379711. Allergan also worked with McKesson on a "bundled promotion consisting of GC phone campaign to 200 customers, a fax blast to 200 customers and a McKesson Connect ad for one week." McCormick Dep., Dkt. # 1966-19, at 283:4-287:18-22 and Ex. 67 (McCormick Dep. Ex. 21). Allergan paid distributors like McKesson to call pharmacies to help sell the generic for Opana ER giving McKesson the opportunity to "earn five times or six times more". McCormick Dep., Dkt. # 1966-19) at 141:10-144:9; Ex. 68 (McCormick Dep. Ex. 8).] They additionally sent direct mailers to the top 10,000 prescribing doctors of Opana ER.[24] Boothe Dep. Dkt. # 1959-6, at 233:7-24; Ex. 62 (Boothe Dep. Ex. 14).

These strategies appear to have paid off: Allergan, through its Actavis entities, commanded approximately 25% of the opioid market for combined between Cuyahoga and Summit Counties from 2006-2014, according to the ARCOS data.[25]

Allergan's generic opioid marketing was aggressive and misleading. Allergan ignored the dangers of opioids known to it and flouted its responsibilities instead sought solely to maximize profits, which contributed to flooding the market in Ohio and nationally.

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[24] Allergan also promoted its generic opioid drugs by implementing strategic points /rebate plans whereby their customers received points and rebates as high as 15% for selling their generic drugs under what was called a "Choice program," and the opioid products were associated with higher amounts of points. It implemented pricing and incentive programs with customers and offered store discounts through its suppliers, like McKesson (McCormick Dep., Dkt. # 1966-19, at 137:3-138:22; Ex. 68 (McCormick Dep. Ex. 8)), through email blasts to pharmacies facilitated by third parties such as PDQ and PharmAlert (McCormick Dep., Dkt. # 1966-19, at 250:19-251:2; Ex. 66 McCormick (Dep. Ex. 17)); by using fliers for their generic opioid drugs (McCormick Dep., Dkt. # 1966-19, at 248:3-249:2; Ex. 57 (McCormick Dep. Ex. 22)), by telemarketing through Anda's call center for oxymorphone, by using ad slicks and sizzle slides (presented at NACDS), and by setting up booths at conferences and tradeshows with the Big 3 distributors and pharmacies and passing out sell sheets. McCormick Dep., Dkt. # 1966-19, at 52:22-53:11, 86:9-18; 93:1-6), 132:18-135:24).

[25] *See* Ex. 69 (Cuyahoga and Summit "Labeler Market Share of 4 Opioid Drugs, etc." and "Vertical Integration of Chain of Distributor Total Dosage Units" charts, excerpted from the ARCOS data for the 2006-2014 time period).

D. TEVA

Teva engaged in extensive misleading unbranded marketing of its opioid products, thereby benefitting both its name-brand and generic opioid products. Teva has been selling name-brand and generic opioid products since 1980 (and Schedule II opioids since 1997), including generic opioids it acquired when it merged with Ivax Corporation in 2006 and Barr Pharmaceuticals in 1998, and branded fast acting fentanyl-based products (Actiq and Fentora) when it merged with Cephalon, Inc. in 2011. Ex. 70 ("Our History", Teva https://www.tevausa.com/About-Teva/article-pages/Our-history/). In 2016, Teva Ltd. acquired the Actavis entities which it purchased Allergan plc's generic pharmaceutical drug business for $40.5 billion.[26] As set forth above, the Actavis entities had approximately 25% of the Cuyahoga and Summit Counties' opioid markets from 2006-2014. With the Actavis acquisition, Teva is the largest generic drug maker in the United States, whose pharmaceutical drugs fill 1 in 6 prescriptions.[27]

Teva engaged in a sophisticated unbranded marketing campaign through front groups, speakers, and CME programs, and the propagation of disease awareness information[28] through the internet and written materials about the treatment of pain using opioids. These campaigns, with little or no disclosure of Teva's sponsorship, advocated to doctors, patients and the medical community generally that opioids were appropriate for a wide range of and other pain while marginalizing the addiction, misuse, and diversion risks associated with these high-risk narcotic drugs.

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[26] For a discussion of the interrelationship among the Teva entities, *see* Pls.' Mem. in Opp. to Teva and Actavis Generic Defs.' Mot. For Summ. J.

[27] Ex. 71 (Doron Herman Dep. (06/20/19) Dep. Ex. 42) at 11 ("Welcome to Teva Pharmaceuticals Industries Ltd. 2017")

[28] For example, Teva's subsidiary Cephalon used disease awareness information to expand overall demand for opioids by applying the concept of opioid treatment for "breakthrough" cancer pain to patients suffering from chronic non-cancer pain—a much larger patient pool. The goal was to convince prescribers that short-acting opioids, like fentanyl, were appropriate and safe to give to chronic pain patients *already on long-acting opioids*, if that patient was experiencing "breakthrough pain." One of the primary mechanisms for this message was KOL promotion. In 2006, Cephalon funded a telephone survey, conducted by Dr. Russell Portenoy and other physicians who were paid consultants for Cephalon and on Cephalon's speakers' bureau, with the reported finding that "breakthrough" pain was prevalent in patients with chronic non-cancer pain. This was followed by other Cephalon-funded studies and KOL promotion of "breakthrough pain" with respect to chronic pain and the use of short-acting opioids on top of long-acting opioids—promotion that was not specific to a particular drug, but which increased the demand for both branded and generic short-acting opioids.

For example, Teva worked with patient advocacy front groups to spread its misleading marketing messages advocating wide range opioid use and minimizing addiction risks. Teva sought to increase its KOL and front group promotion, hiring a public relations agency to conduct an analysis in 2013 of potential KOLs and advocacy organizations who could spread Teva and Cephalon's unbranded marketing messages advocating the use of opioids for the treatment of pain. *See* Ex. 72 (TEVA_MDL_A_00499645) & Ex. 73(TEVA_MDL_A_00499646) (presentation entitled "Teva Advocacy Mapping: Identifying Advocacy Partners to Enhance Patient Care").

Teva was especially active in funding and promoting opioid use through the American Pain Foundation ("APF") front group. On November 18, 2011, Teva representatives met with representatives of APF about the Pain Care Forum, its *Exit Wounds* publication, and other opioid advocacy issues.[29] In 2014, Teva budgeted $100,000 for *Exit Wounds*, and noted that the book was being used by Teva Government Affairs in "raising awareness of the issues specific to veterans living with chronic pain," even though it sold no name-brand opioid at the time that treated pain.[30] In 2017, Teva contracted with a publisher to "edit, publish and distribute the 2nd edition of *Exit Wounds*," and in 2018 paid its author for his time and expenses to promote the book in the media.[31] Teva also sponsored other publications through APF which advocated opioid use for pain and minimized their addiction risks.[32] All the while, the APF was misleadingly portrayed as "[a]n

[29] Ex. 74 (TEVA_MDL_A_01207131 and at TEVA_MDL_A_01207133).

[30] Ex. 75 (TEVA_MDL_A_02965173); Ex. 76 (TEVA_MDL_A_01088080).

[31] Ex. 77 (TEVA_MDL_A_03437093) [excerpt]; (Due to the size of the spreadsheet when printed (>10,000 pages), Plaintiffs are attaching only the relevant cell t as an exhibit, but are happy to provide the full document in the event that there is a dispute as to the document or its authenticity.)Ex. 78 (TEVA_MDL_A_01136278).

[32] For example, Teva sponsored an APF booklet entitled "Treatment Options: A Guide for People Living with Pain, which minimized the opioid addiction risks (stating "physical dependence is normal. … this does NOT mean you are addicted," and blaming addiction on patients who have "lost control" and are "engaging in unacceptable behaviors," and that "Restricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."); *see also* Ex. 79 (TEVA_MDL_A_01090493).

independent, nonprofit organization serving people with pain through information, advocacy and support."[33]

Teva also engaged in an unbranded marketing campaign starting around 2015 called "Pain Matters" to promote disease awareness and to advocate the broad use of opioids to treat and other pain, without appropriately disclosing their addiction risks. The campaign included unbranded internet messaging through its painmatters.com advocacy website.[34] The campaign also sponsored "Pain Matters" events at which it carefully choreographed the speakers' messages concerning broad opioid use and minimization of their addiction risks. For example, the video script for one such event blamed patients who were already addicts and who combined their opioid use with other drugs, and stated abuse and addiction are "relatively low for patients with non-malignant pain who don't have a previous history of addiction."[35]

In another example, Teva's subsidiary, Cephalon, sponsored a campaign called "Emerging Solutions in Pain," which included an "ESP Patient Toolkit – All About Opioids" falsely declaring that "[o]pioid addiction is rare in patients with chronic pain." Ex. 86(TEVA_MDL_A_09545105). The same Patient Toolkit asserted that "[s]ome symptoms look like addiction, but they are not"—"includ[ing] tolerance, physical dependence, and pseudo (or false) addiction." *Id.* In addition, a 2008 presentation about opioid medications generally and directed at physicians stated that "Iatrogenic addiction is very rare." Ex. 87 (TEVA_MDL_A_00907192).

Teva also engaged in other widespread unbranded marketing of its opioids. In addition to the APF, Teva made large payments to a number of third party patient pain groups for their

[33] Ex. 80 (TEVA_MDL_A_ 01207133).

[34] Ex. 81 (TEVA_MDL_A_00765944) (re "Pain Matters" website); Ex. 82 (TEVA_MDL_A_08657218); Ex. 83 (Day Dep. Ex. 5 (TEVA_MDL_A_0865734)); Mathew Day Dep. (01/4/19) Dkt. #1976-11, at 87-89, 225-260 (discussing "Pain Matters" campaign) and Ex. 84 (Day Dep. Ex. 26).

[35] Ex. 85 (TEVA_MDL_A_08652504) (Teva "Pain Matters: Evolving Roles, Same Goals and Video Script" for Teva speakers).

advocacy on pain and opioids.[36] Teva had an extensive speakers program whereby it recruited, trained and paid speakers in the fields of pain management to advocate for widespread use of opioids to treat and other types of pain.[37] Teva had an extensive educational grant program to disseminate its marketing and disease awareness messages concerning the use of opioids to treat pain.[38] Teva sponsored CME programs to acclimate doctors to use opioids for many types of pain, and downplaying the addiction risks as "pseudoaddiction" that required the administration of even more pain medication.[39] Teva spread its unbranded and disease awareness (pain) marketing messages at major professional conferences.[40] Teva prepared patient materials to dispel concerns about the addiction risks of opioids to treat pain.[41] In short, there is substantial evidence Teva engaged in significant fraudulent marketing activities to promote its opioid products, including generics. The evidence submitted is by no means exhaustive, but it is more than enough to raise at least a genuine dispute of material fact as to Teva's liability for harm caused by its generic opioid products resulting from its aggressive and misleading marketing.

II. PLAINTIFFS' STATE LAW CLAIMS ARE NOT PREEMPTED BY FEDERAL DRUG REGULATIONS OR UNDER *MENSING*

Defendants claim that Plaintiffs' state law claims are preempted by federal regulations which precluded Defendants from taking any action to inform prescribers of the proper uses and risks associated with opioids. But this Court has already found claims based on aggressive and misleading

[36] Ex. 88 (TEVA_MDL_A_02401119).

[37] Ex. 89 (TEVA_MDL_A_00877813); Ex. 90 (TEVA_MDL_A_02214252); Ex. 91 (TEVA_MDL_A_03413816); Ex. 92 (TEVA_MDL_A_01108894)

[38] Ex. 93 (TEVA_MDL_A_00565051).

[39] Ex. 94 (TEVA_MDL_A_00844073) "Teaching Series, Continuing Medical Education: Persistent and Breakthrough Pain" at 14 (Wendy) and 61 (Gordon) (providing attending clinicians with two patient case studies with addictive behavior explained as being "pseudoaddiction, a syndrome that results from undertreatment of pain and should be distinguished from addiction and diversion").

[40] Ex. 95.

[41] Ex. 96 (TEVA_MDL_A_01402424) at 4, "Breakthrough Pain: Do you still have pain?" brochure for patients, "Get Rid of Common Myths About Pain: … Concerns about addiction should NOT prevent proper pain management.").

marketing by generic manufacturers not preempted. *See* Op. and Order, June 13, 2019, Dkt. # 1680, at 2. And, here, Plaintiffs do not assert Defendants should have changed the labels or otherwise make statements prohibited by federal law.[42] To the contrary, Plaintiffs contend that Defendants voluntarily made affirmative marketing representations beyond the labels that were false and misleading; such statements were not compelled by federal law.

Relying on *PLIVA v. Mensing*, 564 U.S. 604 (2011), Defendants argue that any state law claim against them would be preempted because it was "impossible" for them to conform to both federal regulations and state law. As the Supreme Court noted, the defendant has the burden of establishing its preemption defenses and, in particular, "[i]mpossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 568-69, 573 (2008). Defendants fail to meet their burden here; Plaintiffs make no claims that impose any obligation on Defendants that would conflict with federal regulations such that they would be preempted under *Mensing*.

Mensing concerned the plaintiffs' claims that the manufacturer failed to change its generic drug label to add new safety information or to otherwise disseminate such new information that is not contained in the approved drug label for the branded drug. *Mensing*, 564 U.S. at 611-12. Because federal regulations require a generic label at all times to be the same as the approved labeling for the equivalent branded drug. *Id.* at 612-13 (citing 21 U.S.C. 355(j)(2)(A)(i)). For this reason, the Supreme Court in *Mensing* concluded state law claims that require a generic manufacturer to add new safety

[42] Moreover, Plaintiffs' claims arising under federal Racketeering and Corrupt Influence statutes (RICO) related to Defendants' marketing conduct and other conduct are also not precluded. *Conley v. Cent. Mortg. Co.*, 414 B.R. 157, 159-60 (E.D. Mich. 2009) (citing *Norfolk W.R. Co. v. Public Utilities Com.*, 926 F.2d 567, 570 (6th Cir. 1991)); *Baker v. IBP, Inc.*, 357 F.3d 685, 688 (7th Cir. 2004); *Ray v. Spirit Airlines, Inc.*, 767 F.3d 1220, 1224 (11th Cir. 2014).

information to its label or to disseminate such new information without a corresponding change to the approved brand label are preempted.[43] *Mensing*, 564 U.S. at 615, 618-19.

Plaintiffs are not claiming Defendants should have changed their generic drug labels or should have affirmatively disseminated information not already contained in the approved labels. Rather, as detailed above, Plaintiffs established that Defendants falsely marketed their drugs through their aggressive marketing efforts, including their unbranded marketing, and Defendants fraudulently concealed the risks associated with their opioids, which include both brand and generic drugs. There is no conflict—and certainly no impossible conflict—between Defendants' obligations under state law to avoid such misconduct as detailed herein and their obligations under federal law to match their generic labels to the labels of the bio-equivalent branded drug products. Simply put, *Mensing* has no application here.

III. CONCLUSION

Generic Defendants engaged in extensive deceitful and misleading conduct that was calculated to fundamentally impact the way the American medical community and the public viewed opioids and their risks. And their efforts worked. Because of Defendants' and their corporate families' misconduct, the market for opioids grew drastically, with that demand filled primarily by Defendants' generic opioids – including 68 billion opioids pills in a single six-year period. Defendants should not be permitted to escape accountability for their wrongful conduct. The law and the facts do not support Defendants' Motion for Partial Summary Judgment. Accordingly, Plaintiffs respectfully submit that the Court should deny Defendants' Motion.

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[43] The Sixth Circuit has held, however, that a state law claim for failure to warn was not preempted where the generic manufacturer failed to update its label to match the label on the branded equivalent, further underscoring that the mere existence of a drug label does not preempt all claims related to generic drug manufacturers' marketing conduct. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). Moreover, a generic drug manufacturer may disseminate information that is "consistent with and not contrary to the relevant 'approved or permitted labeling' . . . ." Brief for the United States as Amicus Curie at 5, *Teva Pharms. v. Superior Court*, 217 Cal. App. 4th 96 (Cal. Ct. App. 2013), 2014 WL 7169712, (rejecting Teva's argument that it could not disseminate safety information consistent with its generic drug label and the corresponding approved name-brand label).

Respectfully Submitted:

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